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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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WORKGROUP ON COMPOUNDING

DECEMBER 1, 2004 MEETING MATERIALS

GENERAL COMPOUNDING PROPOSAL

PROPOSED STATUTORY AND REGULATORY CHANGES

Section 4019.5 of the Business and Professions Code is added to read:

"Compounding" means any the following activities occurring in a pharmacy:

(1) Altering the dosage form or delivery system of a drug.
(2) Altering the strength of a drug.
(3) Combining active ingredients.
(4) Preparing a drug from bulk chemicals.

Section 4033 of the Business and Professions Code is amended to read:

4033. ~~(a) "Manufacturer"~~ "Manufacture" means ~~and includes~~ the preparation, derivation, production, compounding or repackaging of ~~every person who prepares, derives, produces, compounds, or repackages~~ any drug or device except ~~a pharmacy that manufactures~~ a drug or device compounded in a pharmacy. ~~on the immediate premises where the drug or device is sold to the ultimate consumer.~~

~~(b) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~

~~(c) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.~~

Section 4037 of the Business and Professions Code is amended to read:

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where dangerous drugs and dangerous devices are stored. ~~prescriptions are compounded.~~ "Pharmacy" includes, but is not limited to, any area, place, or premises ~~described in a~~ licensed ~~issued~~ by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, ~~manufactured,~~ derived, compounded, or repackaged, ~~and from which the controlled substances, dangerous drugs,~~ or ~~dangerous devices~~ are furnished, sold, or dispensed at retail.

(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture,~~ compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

Section 4123 of the Business and Professions Code is amended to read:

4123. ~~Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.~~

Notwithstanding any other provision of law, a pharmacist may:

(a) Compound a drug pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient named in the prescription, provided that the drug is not compounded prior to receipt of the prescription.

(b) Repackage a drug previously dispensed for the patient at the request of the patient or the patient's agent.

~~§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.~~

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~

~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~

~~(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and~~

~~(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.~~

~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~

~~(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.~~

~~§1716.2. Record Requirements--Compounding for Future Furnishing.~~

~~(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:~~

~~(1) The date of preparation.~~

~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

~~(7) The quantity in units of finished products or grams of raw materials.~~

~~(8) The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

Article 4.5 General Compounding

§1735. Definitions

(a) "Integrity" means the drug will retain its effectiveness until the beyond use date noted on the label.

(b) "Quality" means the drug is free of any contaminants and only contains those active ingredients indicated on the label.

(c) "Strength" means the amount of active ingredient in each unit of the drug.

(d) As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

(1) "Reasonable quantity" means that quantity of an unapproved drug which:

(A) is sufficient for that prescriber's office use; and

(B) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(C) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for strength, quality and integrity of the compounded medication.

(2) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.[1]

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, and 4052, Business and Professions Code.

§1735.1. Requirements

(a) Prior to compounding a drug, the dispensing pharmacist shall establish a professional relationship with the prescriber and patient.

(b) A drug may not be compounded without a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Inactive ingredients to be used.
(3) Process and/or procedure used to prepare the drug.
(4) Quality reviews required at each step in preparation of the drug.
(5) Post compounding process or procedures required, if any.
(6) Beyond use dating requirements.

(c) The pharmacist shall be responsible for assuring that the compounded drug retains its strength, quality, and integrity until dispensed.

(d) All chemicals, drug products, and components must be used and stored according to compendial and other applicable requirements to maintain their strength, quality and integrity.

(e) The beyond use date of the finished product must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies of drugs using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(f) A pharmacy may contract with another pharmacy to compound drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the name of the pharmacy that compounded the drug and the information required by Business and Professions Code Section 4076.

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[1] Moved from 1716.1

(g) Pharmacists who compound drugs, or supervise the compounding of drugs, shall be responsible for ensuring that the compounded drug has been prepared, labeled, stored, and delivered properly.

(h) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(i) A pharmacy may compound drugs in quantities larger than required for immediate dispensing or for prescriber office use.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4052, and 4076, Business and Professions Code.

§1735.2. Records

(a) For each compounded drug a record shall be made that includes at least the following elements:

(1) The information required of a master formula record.
(2) The date the drug was compounded.
(3) The identity of the pharmacy personnel who compounded the drug.
(4) The identity of the pharmacist reviewing the final product.
(5) The quantity of each component used compounding a drug.
(6) The supplier and lot number of each component.
(7) The equipment used compounding a drug.
(8) The internal reference (lot) number.
(9) The expiration date of the final drug.
(10) The quantity or amount of drug product compounded.

(b) Pharmacies must maintain records of the acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding.

(c) The chemicals, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall maintain certificates of purity or analysis for components, chemicals, or drug products used in compounding. Certificates of purity or analysis are not required for drugs used in compounding that are approved by the Food and Drug Administration.

(d) Pharmacies must prepare, maintain, and retain all records required by this article in the pharmacy in a readily retrievable form for a period of three years from the date the record was created.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005 Business and Professions Code.

§1735.3. Labeling

(a) In addition to labeling information required under Businesss and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active component(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drugs compounded into unit of use containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and a beyond use date.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4076, Business and Professions Code.

§1735.4. Policies and Procedures

(a) Pharmacies must maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures for the pharmacy.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge, who shall document the date when the annual review is completed.

(c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual must also be included.

(d) The policy and procedure manual shall include written documentation of a plan for the recall of dispensed compounded products where subsequent verification demonstrates the potential for adverse effects with continued use of the compounded drug.

(e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding drug shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.

(f) The pharmacist-in-charge shall establish policies and procedures to ensure that compounded drugs have the strength indicated by the label.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4113, Business and Professions Code.

§1735.5. Facilities and Equipment

(a) Pharmacies shall provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug, to also include, where applicable, certification of the facility/equipment.

(b) Equipment shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Equipment used in compounding drug products shall be calibrated prior to use to ensure accuracy. Documentation of calibration shall be recorded in writing.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.6. Training of Staff, Patient and Caregiver

(a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.

(b) The training of pharmacy personnel shall be documented and retained as part of an annual on-going competency evaluation process for pharmacy personnel involved in compounding.

(c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.7. Quality Assurance

(a) Pharmacies shall provide written documentation of the development of and adherence to a quality assurance plan.

(b) The quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.

(c) As part of the quality assurance plan, all qualitiative/quantitative analysis reports for compounded drug drugs shall be retained and collated with the compounding record and master formula.

(d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.